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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,492	07/22/2003	Valerie A. Fadok	2879-73-1	9123

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EXAMINER

STANDLEY, STEVEN H

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 06/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/625,492	Applicant(s) FADOK ET AL.	
	Examiner Steven H. Standley	Art Unit 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 88-109 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 88-109 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 88-92, 98-100, drawn to monovalent antibodies, classified in class 530, subclass 387.1.
 - II. Claims 88, 92-100, drawn to bispecific antibodies, classified in class 530, subclass 387.3.
 - III. Claims 101-104, drawn to a method of stimulating phosphatidyl serine receptor (PSR) by contacting with an antibody, classified in class 424, subclass 130.1.
 - IV. Claims 105-109, drawn to a method of inhibiting PSR by contacting with an antibody, classified in class 424, subclass 133.1.

Inventions I-II and III-IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the method of both activating and inhibiting a receptor by contacting with an antibody can be used to activate or inhibit ionotropic glutamate receptors.

Although there are no provisions under the section for "Relationship of Inventions" in the M.P.E.P. § 806.05 for inventive groups that are directed to different

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methods, restriction is deemed to be proper because these methods appear to constitute distinct inventions for the following reasons: Groups III and IV are directed to methods that are distinct both physically and functionally, and are not required and are not required one for the other. The method of Group III is a method of activation the PSR by contacting with an antibody that activates the PSR. Group IV is a method of inhibiting the PSR by contacting with an antibody that inhibits the PSR. The methods have different goals and use different products and produce different results. Moreover the products of each cannot be used in the other. Therefore a search and examination of the methods of group III and group IV would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Groups I-II are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct. Group I is to antibodies that bind a single epitope on a single molecule and Group II is to antibodies that are engineered such that they have one Heavy and light chain variable region directed to one epitope and the other directed to an entirely different epitope. Thus, the antibodies of Group II have a distinct and non-obvious structure compared to antibodies of Group I. The antibodies are directed to different epitopes and function differently from one another and are not

required for each other. Therefore a search and examination of the methods of group I and group II would constitute an undue burden, since the searches are entirely different and not coextensive, the classifications are different and the subject matter divergent.

Furthermore, within group I or II, restriction to one of the following inventions is required under 35 USC 121:

The inventions are directed to variants of antibodies, which are different antibody products with unique polypeptide sequences and unique variable regions in unique combinations. The different antibody inventions within group I are antibodies directed to distinct and unrelated polypeptide sequences and therefore are patentably distinct. Moreover a search and examination of the antibodies directed to the different proteins would constitute a search burden on the examiner. The different antibody inventions within group II are composed of bi-specific antibodies that binding two different epitopes of the same targeted protein (claim 94) or wherein the antigen binding portion binds one epitope on one protein and another epitope on another protein (claim 95). Each bispecific antibody is distinct and not obvious over the other and each would require further search and examination and would therefore constitute a search burden upon the examiner. The following groups represent patentably distinct antibodies:

1. Antibody that binds an epitope of sequence SEQ ID NO: 3 (from group I).
2. Antibody that binds an epitope of sequence SEQ ID NO: 5.

3. Antibody that binds and epitope of sequence SEQ ID NO: 7.
4. Antibody that binds an epitope of sequence SEQ ID NO: 9.
5. Antibody that binds **two** epitopes of sequence SEQ ID NO: 3 (group II).
6. Antibody that binds **two** epitopes of sequence SEQ ID NO: 5
7. Antibody that binds **two** epitopes of sequence SEQ ID NO: 7
8. Antibody that binds **two** epitopes of sequence SEQ ID NO: 9
9. Antibody to SEQ ID NO: 3 and a receptor that is expressed by a cell which expresses the PS receptor (group II).
10. Antibody to SEQ ID NO: 5 and a receptor that is expressed by a cell which expresses the PS receptor.
11. Antibody to SEQ ID NO: 7 and a receptor that is expressed by a cell which expresses the PS receptor.

12. Antibody to SEQ ID NO: 9 and a receptor that is expressed by a cell which expresses the PS receptor.

Applicant is advised that this is not a requirement to elect a species. Rather, this is a second restriction requirement superimposed upon the requirement to elect from groups I-IV. In order to be fully responsive, Applicant must elect one group from I-IV and should Applicant elect group I or II, one variant from within the elected group from those listed above and recited in claims of groups I or II.

In re Ochiai

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

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Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven Standley whose telephone number is **(571) 272-3432**. The examiner can normally be reached on Monday through Friday, 8:00 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on **(571) 272-0867**.

The fax number for the organization where this application or proceeding is assigned is **703-872-9306**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at **866-217-9197** (toll-free).

Steve Standley, Ph.D.

6/14/06




DAVID S. ROMEO
PRIMARY EXAMINER